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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/634,082	08/08/2000	Keith D. Beaty	47168.08.68USC1	5448

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Daniel J. Burnham
JENKENS & GILCHRIST
1445 Ross Avenue Suite 3200
Dallas, TX 75202-2799

EXAMINER	
WOO, JULIAN W	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/634,082	BEATY, KEITH D.	
	Examiner	Art Unit	
	Julian W. Woo	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *90-120 and 122-142* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *106-109 and 131-136* is/are allowed.

6)☐ Claim(s) *90-105,110-120,122-130,137-142* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 29, 2003 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 137-142 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to line 3 in each of base claims 137 and 139, "said tool" lacks antecedent basis. Additionally, "bone tissue," an unpatentable part of the human body, is claimed as a structural part of the invention (i.e., "a dental implant...engages said bone tissue").

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 90-97 are rejected under 35 U.S.C. 102(e) as being anticipated by Garfinkel (5,577,911). Garfinkel discloses, in the figures and in col. 2, lines 47-63 and in col. 3, lines 19-36, a device for developing a bore in living bone, where the device has an osteotome or compaction tool (14) with a lower end, an upper end, an outer surface, and a central axis within the outer surface for compacting bone, a driving mechanism (20) with a piezoelectric transducer element and a cone-shaped mechanical coupling component (at interface of 22 and 16), a power source ("AC electrical outlet"), coupling means (16) with means for releasing and attaching the tool to the driving mechanism, vibrational motion is the direction of the central axis (see col. 2, lines 40 and 41), a drive rod (22) between the piezoelectric transducer and the coupling means, a tool segment with a constant cross-section (see fig. 4A or 4D), a tool cross-section that is tapered or increases from a lower end to an upper end (see fig. 4D), and a coupling means with a screw element (thread) extending into the tool. Note: The

introductory statement of intended use ("for developing a bore in living bone for receiving a screw-type dental implant") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over Garfinkel's device, which is capable of being used as claimed if one desires to do so.

6. Claims 116-120 and 122-126 are rejected under 35 U.S.C. 102(b) as being anticipated by Idemoto et al. (4,832,683). Idemeto et al. disclose, in figure 6b and in col. 3, lines 37-60, a device and a method for applying the device in developing an elongated bore in a living bone (28), where the device includes a tool having a central axis, a generally circular cutting edge, a gradually expanding region behind the cutting edge, a region of constant diameter (at 30), a conduit (21), and a concave surface (22); a driving mechanism (4) with a piezoelectric (electrostriction) device, and electrical power at a selected frequency and amplitude (see col. 3, lines 37-42), where the cutting edge is configured to cut bone around a circumference of the elongated bore and maintain the bone within the bore (if, for example, the cutting edge is directed into the bore or bone is allowed to drop into the bore) and where the tool is "inserted deeper" into the bone to enlarge the bore.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 98-100, 102, 103, 110-115, 124-125, and 137-142 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn (6,139,320). Hahn discloses the invention substantially as claimed. Hahn discloses in figures 1 and 13 and in col. 2, lines 21-26; col. 4, lines 12-19; and col. 16, lines 53-59; a compaction tool and a method as claimed for developing an elongated bore in a living bone (150), where the method includes the application of an osteotome or compaction tool (154) or a tool, a driving mechanism (16) with a piezoelectric transducer element and vibrational motion (see col. 12, lines 43-45); and where the tool includes a central axis, a sequence of regions from the lower end to the upper end that increases in cross-sectional area or is tapered (at the spherical portion), and regions of constant diameter (152). Hahn also discloses that the geometry of the cavities is a result of the geometric form of the tools forming the

cavities (i.e., the length and width dimension of a formed, elongated bore is defined by the tool). However, Hahn does not disclose installing an implant into the elongated bore. Nevertheless, Hahn also discloses, in col. 1, lines 8-20 that bone replacement material (i.e., materials which can also be used as dental implants with surfaces), is applied in bone cavities formed by work tools. Therefore, it would be obvious to one having ordinary skill in the art to apply bone replacement material to a bone bore that is modified by Hahn's tool. Such an implant would replace weakened or diseased bone removed and displaced by Hahn's tool.

Hahn also does not disclose an osteotome tool engaging living bone substantially along an entire length of a bore in the bone, the tool incrementally compacting bone, and the step of developing a pilot hole before insertion of the tool in the hole. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to engage the tool along the length of the bore. Such a practice would be applied, if upon necessity, a bore is formed that is large enough to accommodate a substantial portion of the tool. Also, formation of the bore inherently causes some compaction of bone material by the tool, so incremental formation of the bore would lead to incremental compaction of the living bone. It would also be obvious to develop a pilot hole before insertion of a tool. A pilot hole would allow positionally precise boring into bone through guidance of the tool along the axis of the hole.

9. Claims 101,104, and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Idemoto et al. Hahn discloses the invention substantially as claimed, but does not disclose a method where the piezoelectric transducer element oscillates when electrical oscillations of a selected frequency and amplitude are produced by electric power and where vibrational motion of the tool has a frequency of 500 Hz. Idemoto et al. teach, in col. 3, lines 37-60, transducer element oscillations from electrical oscillations produced by electric power and variable vibrational motion frequencies. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Idemoto et al., to control the transducer element oscillations via control of electrical power frequencies and choose a vibrational motion frequency of 500 Hz. Such control of transducer element oscillations and the choice of a vibrational motion frequency would be applied according to conditions of the operation to be performed, including for example, tissue hardness.

10. Claim 127-130 are rejected under 35 U.S.C. 103(a) as being unpatentable over Idemoto et al. Idemoto et al. disclose the invention substantially as claimed. Idemoto et al. disclose, in figure 3, cutting edges (23, 24, and 25) being generally perpendicular to the central axis of the tool, but do not disclose a method with a tool having a vibrational motion frequency of about 500 Hz and where the cutting edge develops the bore, while the central axis of the tool is generally perpendicular to the bone adjacent to the bore. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to choose such a frequency. Such a choice would be dependent upon conditions

of the operation to be performed, including for example, tissue hardness. A choice of 500 Hz would be useful for cutting soft tissue without undue damage to the tissue. Also, it would be a matter of design choice in the development of a bore for the central axis of the tool to be generally perpendicular to the bone adjacent to the bore. The choice would be dependent upon the angle of the tool necessary for removing selected portions of bone in order to achieve a desired size and shape of the bore.

Allowable Subject Matter

11. Claims 106-109 and 131-136 are allowed.

12. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses a device for developing in living bone an elongated bore that includes, inter alia, a compaction tool and a driving mechanism with means for vibrationally moving the tool, where the tool has bone-engaging surface having depth markings; and method of installing a dental implant into a bore in living bone, where the method includes developing the bore with an ostetome tool having piezoelectric transducer element as a driving mechanism and where a dental implant in screwed into the bore. None of the prior art of record, alone or in combination discloses, a dental system with, inter alia, a screw-type dental implant and an ostetome tool having a cutting edge and a bone-compacting surface and a piezoelectric transducer element as a driving mechanism.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should

preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Amendment

13. With respect to the rejection of claims based on the references of Garfinkel, Hahn, and Idemoto: See the rejections above. Also with repect to arguments regarding rejections based on Garfinkel: The Examiner agrees that Garfinkel discloses the removal of "granulated tissue" and the avoidance of healthy bone tissue. However, this argument does not deny the fact that periodontal disease can affect bone tissue. Thus, Garfinkel's device is also of capable of boring into diseased bone tissue for its removal. Also with respect to arguments regarding Hahn, dental implants can include "bone replacement material." For example, polymethylmethacrylate (PMMA) is a common biomaterial known for its use in bone and in teeth. The amendment has overcome the rejection of claims 131-133.

With respect to the argument that the Examiner applied "hindsight" construction of prior art to arrive at the present invention: It must be recognized that any judgment on obviousness is in a sense a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper (see In re McLauglin, 443 F.2d 1392; 170 USPQ 209 (CCPA1971)).

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Das (4,365,957) teaches a tool for cutting gingiva and bone. Bray, Jr. (5,586,989) teaches a curette for removing bone.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703)308-0858. The FAX number is (703)872-9302.

Julian W. Woo
Primary Examiner

March 9, 2004